Clinical outcomes in patients with chronic congestive heart failure who undergo left ventricular assist device implantation

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Objective: The use of left ventricular assist devices as a bridge to transplantation for patients with chronic congestive heart failure is well accepted. However, few studies have examined outcomes solely for these patients. This study details one center's left ventricular assist device experience with this population.

Methods: Two hundred one patients received HeartMate left ventricular assist devices (Thoratec Corp, Pleasanton, Calif) from January 1, 1996, to April 30, 2004. Of these, 119 (59.2%) had chronic congestive heart failure (diagnosis >6 months) as the primary indication. Outcome parameters included early mortality after left ventricular assist device placement (<30 days), bridge-to-transplantation rate, and posttransplantation survival. Variables examined included patient demographic data; preoperative pacemaker, internal defibrillator, and balloon pump use; and preoperative laboratory values.

Results: Advanced age, female sex, and diabetes were independent predictors of early death ($P = .048$, odds ratio 1.879 per 10 years of age, 95% confidence interval 1.005-3.515; $P = .002$, odds ratio 10.029, 95% confidence interval 2.256-44.583; $P = .040$, odds ratio 3.974, 95% confidence interval 1.063-14.861). Advanced age, female sex, and low preoperative albumin were independent predictors of poor bridge-to-transplantation rate ($P = .029$, odds ratio 0.135 per 10 years of age, 95% confidence interval 0.022-0.819; $P = .002$, odds ratio 0.013, 95% confidence interval 0.001-0.197; $P = .023$, odds ratio 19.178 per 1 g/dL albumin, 95% confidence interval 1.504-244.598). There were no independent predictors of poor posttransplantation survival and prolonged intensive care unit stay. Overall bridge-to-transplantation rate was 81.5%. The 1-, 3-, 5-, and 7-year posttransplantation survivals were 88.4%, 84.5%, 78.4%, and 76.0%.

Conclusion: Among patients with chronic congestive heart failure, advanced age, female sex, diabetes, and low preoperative albumin predict poor clinical course. Careful risk stratification and comprehensive evaluation by care providers should be performed for candidates who are female, are elderly, and have diabetes, and preoperative nutritional optimization should be encouraged to enhance patient outcomes.

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Read at the Eighty-fifth Annual Meeting of The American Association for Thoracic Surgery, San Francisco, Calif, April 10-13, 2005.

Received for publication March 16, 2005; revisions received July 7, 2005; accepted for publication July 19, 2005.

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J Thorac Cardiovasc Surg 2005;130:1302-9

0022-5223/$30.00

doi:10.1016/j.jtcvs.2005.07.017

The use of left ventricular assist devices (LVADs) as a support option for patients with severe, end-stage heart failure is well accepted. LVADs have found application across a range of heart failure syndromes, both acute and chronic. In the acute setting, they have been successfully used for such entities as

Abbreviations and Acronyms

BSA = body surface area
CHF = congestive heart failure
ICU = intensive care unit
LOS = length of stay
LVAD = left ventricular assist device
REMATCH = Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure

postcardiotomy shock,[1,2] acute myocardial infarction and cardiogenic shock,[3,4] acute myocarditis,[5-7] and peripartum cardiomyopathy.[8] Because of the acute nature of these illnesses, however, morbidity and mortality within this population remain exceedingly high.

Conversely, chronic congestive heart failure (CHF) follows a different clinical course. The nature of the disease is progressively and consistently deteriorating. Although in most patients with chronic CHF, LVADs are in fact intended to bridge to transplantation, the Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) trial recognized permanent, destination LVAD therapy as a valid alternate clinical end point.[9] The proven benefits of LVAD therapy relative to optimal medical management make it likely that more and more elderly patients with heart failure will be referred for LVAD implantation in the future. As such, age-related health factors and comorbidities need to be carefully considered, and patient selection will play an increasingly critical role in the determination of clinical outcomes.

The purpose of this study was to characterize our center's clinical LVAD experience solely with the population being treated for chronic CHF. By identifying preoperative factors that predict postoperative end points, we hoped to optimize preoperative status and tailor selection criteria to enhance patient outcomes.

Patients and Methods

This study protocol was approved by the institutional review board of Columbia University College of Physicians and Surgeons, New York, NY. Data were retrospectively analyzed after databases were stripped of all patient identifiers, and a unique code number was used for each study subject.

Chronic CHF was defined as heart failure diagnosed more than 6 months before LVAD insertion. All patients evaluated for LVAD insertion had New York Heart Association class IV symptoms. Patients with diagnoses for less than 6 months and those who underwent LVAD insertion under acute circumstances (eg, postcardiotomy shock, acute myocardial infarction and cardiogenic shock, acute myocarditis, and peripartum cardiomyopathy) were excluded. Those requiring LVAD insertion for acute heart failure superimposed on underlying chronic heart failure were similarly excluded.

TABLE 1. Clinical characteristics of LVAD recipients with chronic CHF

Characteristic	Value
Age (y, mean ± SD)	52 ± 12
Sex (No.)	
Male	104 (87.4%)
Female	15 (12.6%)
CHF etiology (No.)	
Coronary artery disease	49 (41.1%)
Idiopathic cardiomyopathy	56 (47.1%)
Other	14 (11.8%)
Body mass index (kg/m^2, mean ± SD)	26.7 ± 5.5
Diabetes mellitus (No.)	29 (24.4%)
Hypertension (No.)	32 (26.9%)
Preoperative arrhythmia (No.)	61 (51.3%)
Preoperative pacemaker (No.)	22 (18.5%)
Preoperative automatic implantable cardiac defibrillator (No.)	31 (26.1%)
Smoking history (No.)	39 (32.8%)
Alcohol history (No.)	17 (14.3%)
Preoperative intra-aortic balloon pump (No.)	17 (14.3%)
LVAD risk factor score* (mean ± SD)	2.7 ± 2.7
Blood urea nitrogen (mg/dL, mean ± SD)	45.6 ± 25.3
Creatinine (mg/dL, mean ± SD)	1.9 ± 0.8
Total protein (g/dL, mean ± SD)	6.7 ± 1.0
Albumin (g/dL, mean ± SD)	3.7 ± 0.5
Total bilirubin (mg/dL, mean ± SD)	2.4 ± 2.7
Direct bilirubin (mg/dL, mean ± SD)	0.9 ± 1.4
Aspartate aminotransferase (U/L, mean ± SD)	85.2 ± 174.3
Alanine aminotransferase (U/L, mean ± SD)	97.3 ± 248.3
Alkaline phosphatase (U/L, mean ± SD)	107.9 ± 55.3

CHF, Congestive heart failure; *LVAD,* left ventricular assist device; *SD,* standard deviation. *Out of 10 possible points.

From January 1996 to April 2004, a total of 201 patients underwent HeartMate LVAD (Thoratec Corp, Pleasanton, Calif) insertion at our institution. Of these, 119 (59.2%) had chronic CHF as the primary indication. All patients were under evaluation for cardiac transplantation at the time of LVAD insertion. Thus no patients designated to receive LVADs for permanent, destination therapy were included.

The clinical characteristics of the patients receiving LVADs for chronic CHF are outlined in Table 1. The vast majority of patients (87.4%) were male, and the most common etiology for heart failure was idiopathic (dilated) cardiomyopathy.

Outcome parameters included duration of LVAD support, total hospital length of stay (LOS), intensive care unit (ICU) LOS, post-LVAD early mortality (<30 days), bridge-to-transplantation rate, and posttransplantation survival. Preoperative variables included patient demographic data; pacemaker, automatic implantable cardiac defibrillator, and intra-aortic balloon pump use; LVAD risk factor score; and serum laboratory values. The LVAD risk factor score used derives from a screening scale that identifies preoperative risk factors shown to adversely affect survival after

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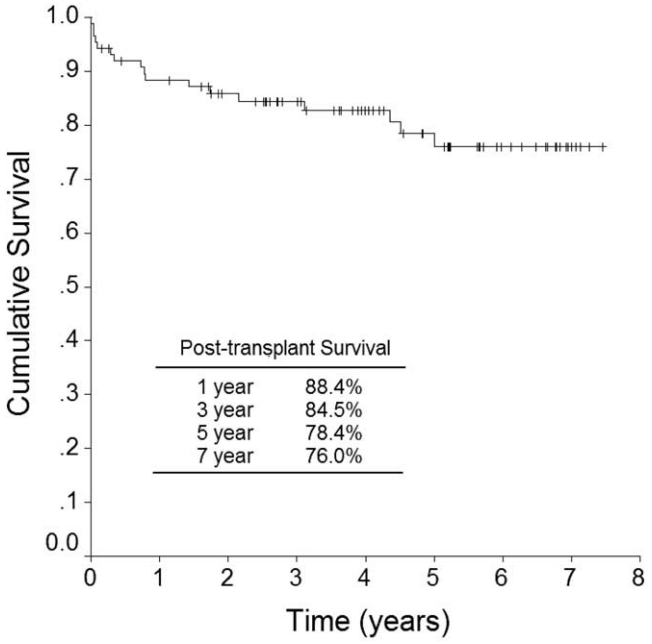

Figure 1. Posttransplantation survival.

LVAD insertion.[10,11] These include ventilation dependence, postcardiotomy shock, previous LVAD, prothrombin time longer than 16 seconds, and central venous pressure greater than 16 mm Hg. LVAD implantation scores are calculated from these five clinical variables, and there is typically an inverse relationship between score and clinical stability. Preoperative serum laboratory values included blood urea nitrogen, creatinine, total protein, albumin, total bilirubin, direct bilirubin, aspartate aminotransferase, alanine aminotransferase, and alkaline phosphatase.

Prediction analyses were run for four clinical outcomes: post-LVAD early mortality (<30 days), prolonged ICU LOS (>14 days), bridge-to-transplantation rate, and posttransplantation survival. Data were examined univariately with the Student *t* test for continuous variables and with the χ^2 test for discrete data. Kaplan-Meier analysis was used to calculate survival. Actuarial survivals at 1, 3, 5, and 7 years after transplantation were calculated by constructing life tables. Variables with a *P* value less than .25 were entered into a logistic regression analysis for multivariable analysis. This multiple regression analysis examined variables with dichotomous outcomes (such as early mortality) and their potential associated risk factors by means of a linearized function of a set of covariates. Risk factors allowed into the final model with a resultant *P* value less than .05 were interpreted as independently associated with the event, above other potential risk factors in the equation. All data were analyzed with SPSS version 11.5 software (SPSS, Inc, Chicago, Ill).

Results

Duration of LVAD Support

The mean duration of LVAD support for all patients was 71 ± 72 days (median 48 days, range 0-448 days). The mean durations of LVAD support until transplantation or death were 81 ± 75 days (median 57.5 days, range 4-448 days) and 28 ± 33 days (median 23 days, range 0-139 days), respectively.

Hospital and ICU LOSs

Mean total hospital LOS was 33 ± 24 days (median 27.5 days, range 0-139 days). Mean ICU LOS was 15 ± 18 days (median 10 days, range 0-139 days).

Clinical Outcomes

Twenty of 119 patients (16.8%) died after LVAD implantation. Thirteen (10.9%) of these deaths occurred within 30 days, and 7 (5.9%) occurred after 30 days. Excluding the 11 patients who were still receiving LVAD support at the end of the study, 88 (81.5%) of 108 patients were successfully bridged to transplantation. All patients in this study were candidates for cardiac transplantation before LVAD insertion, and none underwent LVAD explantation for myocardial recovery. Posttransplantation actuarial survivals at 1, 3, 5, and 7 years were 88.4%, 84.5%, 78.4%, and 76.0%, respectively (Figure 1).

Predictors of Clinical Outcomes

Independent predictors of early death (<30 days) are shown in Table 2. These included advanced age, female sex, and diabetes mellitus. Advanced age predisposed toward early death by 1.9 times for every additional 10 years of age. The presence of diabetes mellitus increased early mortality nearly 4 times, yet the greatest risk factor was female sex (women were 10 times more likely to die than their male counterparts). The clinical characteristics of all female patients with LVADs are shown in Table 3.

TABLE 2. Multivariate analysis: Independent predictors of early death

Risk factor	Variable estimate	SE	*P* value	OR	95% CI
Age	0.631	0.319	.048	1.879*	1.005-3.515
Female sex	2.305	0.761	.002	10.029	2.256-44.583
Diabetes	1.380	0.673	.040	3.974	1.063-14.861

SE, Standard error; *OR,* odds ratio; *CI,* confidence interval. Hosmer-Lemeshow goodness-of-fit test *P* value .722. *Odds ratio for every 10-year increase in age.

TABLE 3. Clinical characteristics of female LVAD recipients

Patient	Age (y)	Diagnosis	Previous cardiotomy	Support time (d)	Status*	Cause of death
1	65	ICM	No	3	Died	MSOF
2	63	ICM	No	2	Died	Right ventricular failure
3	59	CAD	Yes	124	Transplant	NA
4	32	ICM	No	58	Transplant	NA
5	61	Viral CM, CAD	Yes	12	Died	Hemorrhage from aorta–left atrium fistula, dissection
6	60	CAD	No	47	Died	Sepsis
7	57	ICM	No	105	Transplant	NA
8	55	CAD	No	30	Transplant	NA
9	27	Postpartum CM	No	101	Transplant	NA
10	58	CAD	Yes	32	Transplant	NA
11	48	Amyloidosis	No	25	Died	Large cerebrovascular accident
12	62	ICM	No	16	Died	MSOF
13	57	Doxorubicin-induced CM	No	77	Died	Sepsis
14	56	Dilated CM	No	21	Died	Biventricular failure
15	57	Rheumatic valvular CM	Yes	31	Ongoing	NA

ICM, Idiopathic cardiomyopathy; *MSOF,* multisystem organ failure; *CAD,* coronary artery disease; *NA,* not applicable; *CM,* cardiomyopathy. *At end of study.

Independent predictors of bridge to transplantation are shown in Table 4. Advanced age, female sex, and low preoperative serum albumin predicted a poor bridge-to-transplantation rate. For every 10-year increase in age, the likelihood of bridging to transplantation was reduced by a factor of 0.135 (odds ratio). For every 1-g/dL increase in preoperative serum albumin level, there was a 19.2 times greater likelihood of bridging to transplantation. The odds ratio for female patients successfully bridging to transplantation was a mere 0.013.

There were no independent predictors of prolonged ICU LOS or posttransplantation survival.

Discussion

The number of patients who underwent LVAD insertion on an emergency basis at our institution has gone down during recent years. Previously, we reported that 73 of 115 patients (63%) had required emergency LVAD placement during a 6-year period.[12] The remaining 37% received LVADs in a nonurgent setting. In this study, the reverse was true, with 119 of 201 patients (59%) in an 8-year period undergoing nonurgent LVAD placement and the remaining 41% of patients undergoing emergency placement. The reasons for this shift in the urgency setting of LVAD implantation may have to do with a greater number of referrals for LVAD placement of patients with chronic CHF relative to patients with acute heart failure. As LVADs continue to gain wider recognition as a definitive mode of therapy for chronic CHF, we anticipate this shift toward implanting them on a nonurgent basis to become even more pronounced.

Overall, the clinical outcomes of this patient cohort compared favorably with those of other large LVAD experiences. The bridge-to-transplantation success rate of 81.5% was greater than the 60% to 73% rate reported in other studies,[13-15] although it is true that those studies also included patients receiving LVADs for acute heart failure, which carries a higher mortality in general. Among those who were successfully bridged to transplantation, posttransplantation survivals were equivalent to those reported in other LVAD studies[13-15] and to those attained by transplant recipients bridged by medical therapy alone.[16]

Advanced age was determined to be an independent predictor of both early death and poor bridge to transplantation. The mean age in this study was 52 ± 12 years (median 55 years), although there were 32 patients older than 60 years, and the oldest patient included was 69 years old. The negative influence of increasing age has also been reported in other studies. Deng and colleauges[17] found that age greater than 65 years was a significant risk factor for death in a study of 464 patients with end-stage heart failure who received the Novacor LVAD. Frazier and associates[18] noted age to be a risk factor for poor survival to transplantation in a multicenter analysis of 280 patients with the HeartMate LVAD. More recently, Jurmann and colleagues[19] described a 37% 30-day post-LVAD mortality among patients older than 60 years and with contraindications to cardiac transplantation. Although there are no absolute exclusion criteria for LVAD implantation by age alone among bridge-to-transplantation candidates, many surgeons accept 65 years as a reasonable cutoff. This threshold relates, at least in part, to the fact that age greater than 65 years is a contraindication to cardiac transplantation at most institutions. This principle was upheld in the REMATCH trial; patients who were designated to receive

TABLE 4. Multivariate analysis: Independent predictors of bridge to transplantation

Risk factor	Variable estimate	SE	*P* value	OR	95% CI
Age	−2.006	0.921	.029	0.135*	0.022-0.819
Female sex	−4.341	1.387	.002	0.013	0.001-0.197
Albumin	2.954	1.299	.023	19.178†	1.504-244.598

SE, Standard error; *OR,* odds ratio; *CI,* confidence interval. Hosmer-Lemeshow goodness-of-fit test *P* value = .604. *Odds ratio for every 10-year increase in age. †Odds ratio for every 1-g/dL increase in serum albumin level.

LVADs as permanent, destination therapy qualified for the study specifically because they were not candidates for transplantation. In that study, the mean age was 66 ± 9 years, and advanced age was the most common reason for ineligibility for transplantation. Although patients aged 60 to 69 years who received LVADs had a 1-year survival inferior to those younger than 60 years (47% vs 74%), their survival was still superior to their 60- to 69-year-old counterparts who received medical therapy (15%). With similar logic, LVAD placement in 60- to 69-year-old bridge-to-transplantation candidates may not yield the same survival as placement into patients younger than 60 years, but survival may still be sufficient to justify the effort. The use of LVADs in this regard may therefore lead to selection of only the most well-suited patients for transplantation, a process that ultimately might dictate the more judicious allocation of allografts.

Female sex was also determined to be an independent predictor of both early death and poor bridge to transplantation. Although there were only 15 female LVAD recipients, 8 (53.3%) of them died, and only 6 of 14 (42.9%) were successfully bridged to transplantation (1 patient was still receiving LVAD support at the end of the study). Much attention has previously been directed toward female sex as an independent risk factor for death after coronary artery bypass grafting,[20,21] although recent opinion holds that prevalence of comorbid risk factors in women, not gender per se, is what truly affects these midterm and long-term survivals.[22] Higher mortality has also been reported among female LVAD recipients,[23] and the purported reasons have again been considered to be related to gender differences in disease epidemiology and timeliness of heart failure management. Smaller body size has been associated with increased operative mortality.[24] Although the female patients in this study did, in fact, have lower body surface areas (BSAs) than their male counterparts (1.8 ± 0.2 m^2 vs 2.0 ± 0.2 m^2, $P < .01$), only 1 female patient actually had a BSA less than 1.5 m^2, the lower limit indicated for HeartMate implantable LVADs. Still, lower BSA in general may contribute to adverse outcomes as a result of diminished capacity to accommodate the device, more pronounced posterior displacement of the stomach, and impaired wound healing. Other important factors that could contribute to higher mortality among female recipients include relatively longer waiting times to transplantation because of more stringent donor-recipient size-matching criteria and a greater propensity toward psychosocial disturbance after the operation.[25] Further investigation into these issues, among other gender-based anatomic and physiologic differences, is warranted to facilitate understanding and mediation of these disparate clinical outcomes.

Diabetes mellitus was present in 29 of 119 patients (24.4%) and conferred a near 4-fold increased risk for early death. The concern with diabetes in patients receiving LVADs rests on two grounds: its frequent comorbidity with damage of other end organs, particularly the kidneys, and the potential for accelerated allograft vasculopathy in patients who are ultimately bridged to transplantation. Type 1 diabetes mellitus with end-organ damage is in fact a contraindication to transplantation, and this policy stems from concern regarding increased infection during immunosuppression therapy, increased metabolic derangements, and the development of transplant coronary artery disease.[26] The REMATCH trial excluded neither elderly patients nor those with diabetes from receiving LVADs for destination therapy. Improved long-term survival data for these patients with diabetes would allow us to be more optimistic about outcomes in the bridge-to-transplantation population, but until these improvements are realized, only the most carefully selected patients with diabetes, those with minimal comorbidities, should be considered for LVAD implantation, and there must be vigilant management of diabetes during the postoperative period.

Preoperative serum albumin was used as a surrogate for nutritional status and was found to be an independent predictor of bridge to transplantation. This association was marked, with a nearly 20-fold increase in bridge rate for every 1-g/dL increase in serum albumin. The significance of nutritional status in the patient with LVAD implantation is often overlooked in the context of more acute management issues but has gained recognition as a target area for improvement. Much of this focus comes from observations that poor nutritional status is associated with increased morbidity and mortality among surgical patients in general, but particularly the elderly population. In this regard, LVAD implantation qualifies as among the most serious of physiologic insults, because it represents highly invasive

surgery in frequently malnourished, debilitated elderly patients in a chronic inflammatory state.

Preoperative malnutrition predisposes LVAD recipients toward a range of infectious complications and impaired wound healing. The true extent to which infectious complications develop as a direct result of preoperative malnutrition is not known, but there seems to be a clear positive indication, both from a clinical and an economic standpoint, for reversing the long-term effects of malnutrition to restore immunologic function.[27]

The importance of nutritional assessment has been looked at previously[28] and focuses on accurate evaluation of a patient's preoperative nutritional status. In addition to serum albumin levels, serial assessments should also be made of prealbumin, transferrin, retinol-binding protein, total and absolute lymphocyte counts, and C-reactive protein. The goal for patients scheduled for LVAD implantation on a nonurgent basis would be to provide nutritional supplementation according to individual caloric and substrate needs. Once patients have optimal nutrition, they can then enter their operation at less of a disadvantage; however, they should continue with nutritional supplementation (preferably enterally delivered) well into the intermediate postoperative period.

In contrast to studies by other large LVAD centers,[29,30] preoperative variables not identified as risk factors for early mortality or lower bridge-to-transplantation rate included etiology of heart failure, lower BSA, elevated blood urea nitrogen, creatinine and total bilirubin levels, reoperation status, and recent LVAD use. However, it is important to note that these other studies included patients with acute heart failure in addition to those with chronic CHF, which affects clinical characteristics considerably. These differences in risk factors are reflected in the distribution of heart failure etiology alone in the study populations; whereas other centers have reported that upward of 69% of LVAD recipients have ischemic cardiomyopathy, we report a greater number of patients whose cardiomyopathy is idiopathic (47%) than ischemic (41%) in nature. This difference in disease etiology, among multiple other factors, may have important implications regarding the likelihood and nature of previous cardiac surgery procedures, as well as any preoperative embarrassment of end-organ function. When looking at both acute and chronic heart failure patients, our experience is comparable to those of other centers with similarly identified preoperative risk factors for mortality.[10,11]

Study Limitations

This was a retrospective analysis that selected patients who had received LVADs and worked backward to identify the exact indications for insertion. Data collection was not complete in all fields and cannot be as accurate as that obtained in a prospective clinical trial. Because the number of preoperative variables was limited, the study potentially misses stronger independent predictors of mortality, or even important covariates that might otherwise have negated the predictors identified in this study.

We defined chronic CHF as heart failure that had been diagnosed for longer than 6 months before LVAD insertion. Although this time frame is sufficient in most cases to validate a diagnosis of chronic CHF, particularly when coupled with a thorough cardiac transplantation evaluation, it excludes patients with diagnoses of heart failure for less than 6 months. A similar selection bias is introduced by excluding all patients who had acute CHF superimposed on chronic CHF necessitating LVAD insertion.

Our inclusion of preoperative diabetic status failed to discern between type 1 and type 2 subtypes of diabetes mellitus. This is an important distinction, because these groups often have different pathologic mechanisms, disease manifestations, comorbidities, and approaches to management. Preoperative serum albumin was selected as a general surrogate for nutritional status, whereas in fact there are a number of other serum markers and diagnostic tests that collectively provide a more accurate representation. These include, for example, serum prealbumin, transferrin, retinol-binding protein, total and absolute lymphocyte counts, skinfold thickness measurements, indirect calorimetry, and dual-energy x-ray absorptiometric scans. Again, however, the retrospective nature of this study precluded collection of such comprehensive data, and we were therefore constrained to use cruder parameters.

Conclusions

Among patients with chronic CHF who undergo LVAD insertion as a bridge to transplantation, advanced age, female sex, diabetes, and low preoperative serum albumin predict poor clinical course. Careful risk stratification and comprehensive evaluation by care providers should be performed for elderly candidates and those with diabetes. Further investigation into gender-based heart failure management issues, as well as anatomic and physiologic differences, is warranted to gain insight to the reasons behind worse outcomes in female patients. Preoperative nutritional optimization will play an increasingly important role in curbing device-related infections and promoting proper wound healing.

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CSP

Discussion

Dr Robert C. Robbins *(Stanford, Calif).* I am struggling a bit to understand what is really new here. Now you are going to tell me, you looked at your overall experience and are taking just about the chronic cases. So help me understand a little better about what these patients actually were really like. I am assuming they were all in the hospital, in the ICU, with intravenous lines.

Dr Dang. All of them had New York Heart Association class IV symptoms. They may not necessarily all have been inpatients, but for the most part we tried to select patients who received implants less on an emergency basis and more on a nonurgent basis.

Dr Robbins. I can understand that part, but what you just said would lead me to believe there were a few patients who came from home to have the LVAD placed, sort of semielectively? This was probably not the case. So my question concerns the definition of having heart failure for longer than 6 months; what does that really mean? Does that mean they had been seen in your clinic, had been treated by a physician?

One of the things you could do is say, as you did in your article and I was trying to get you to say here, is that they were receiving β-blockers and all those kinds of things. I would just like to better define the population.

Dr Dang. Thank you for the clarification.

Dr Georg Lutter *(Kiel, Germany).* I totally agree with Dr Robbins. I have two questions: First, as listeners, we would like to know about the etiology of the chronic CHF. Second, did you also see patients who were bridged to recovery? Did they all undergo heart transplantation, or did you also see patients in whom a combination of an assist device and a coronary artery bypass grafting were performed, or did you do subsequent procedures in these patients to let them recover?

Dr Dang. Thank you for the question, Dr Lutter. As far as bridge to recovery, such patients were excluded. There were ac-

tually few of them. Of the 200 patients at whom we looked initially, there were probably only 4 who were bridged successfully to recovery. All patients intended to bridge to transplantation were included, and none underwent concomitant procedures with LVAD insertion.

Dr Lutter. What was the etiology of the chronic CHF?

Dr Dang. Most of these cases were ischemic and idiopathic in nature.

Dr John G. Byrne *(Nashville, Tenn).* Have you considered looking at trying to develop a scoring system to weigh these various risk factors? You had an odds ratio of 20 in one case, an odds ratio of 2 or 3 in other cases. Say you gave 3 points for an odds ratio of 20, and so forth. So if a patient has advanced age, female sex, diabetes, and malnutrition, you probably should not place an LVAD, but if a patient has one or maybe two of these factors, you would think about it. That may mean combining your database with other, larger databases.

Dr Dang. Thank you, Dr Byrne. That is an excellent point. An LVAD scoring system does exist for all potential LVAD recipients; this was actually developed at our center. But the issue with that LVAD scoring system is that it also includes patients with acute heart failure, many of whom cannot be controlled for preoperatively.

I think it makes a lot of sense to develop a scoring system specifically for patients with chronic heart failure who, when receiving an implant on a nonurgent basis, could have their status optimized preoperatively in such areas as nutrition and diabetic management. We are in the process of trying to put together a scoring system that includes some of these risk factors.

Dr Mark J. Krasna *(Baltimore, Md).* You pointed out the importance of nutrition. I am wondering how you have changed your clinical evaluation to take that into account. Obviously, you measured albumin. There are a lot of other more sensitive ways to do that. What are you currently doing?

Dr Dang. We are presently running a clinical trial at our center that seeks to determine whether there is a role for immune-enhanced nutritional supplementation in the perioperative period for the purpose of lowering infection rates.

With respect to following nutritional status, we get preoperative laboratory values and then test again at various postoperative intervals, from 1 to 16 weeks. Different nutritional parameters are assessed, including albumin and prealbumin, as are inflammatory markers such as C-reactive protein. We also look at other protein markers, such as retinol-binding protein and transferrin. Finally, we obtain dual-energy x-ray absorptiometric scans both before the operation and 16 weeks after it. Dual-energy x-ray absorptiometric scans have previously been used to assess bone density, but they are also useful in assessing peripheral lean body mass, particularly changes in body mass during the course of LVAD support.